

EXHIBIT 1

**RECEIVED
CENTRAL FAX CENTER**

FEB 16 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED
CENTRAL FAX CENTER

FEB 16 2005

In re Application of: Shacknai, et al

Serial No. 10/829,426

Attorney Docket No.: 00-40175-US-P2DC

Filing Date: April 21, 2004

COMPOSITIONS AND METHODS
FOR HIGH SORPTION OF SKIN
MATERIALS AND DELIVERY OF
SULFUR

DECLARATION OF HOWARD MAIBACH, Ph. D.

I, Howard Maibach, Ph.D., do hereby declare that:

1. I am aware that the U.S. Patent and Trademark Office Examiner has rejected the above-identified patent application because the Examiner believes that sulfur may be toxic above a concentration of 6%.
2. The Examiner cited my July 1990, letter to the editor in the Journal of the American Academy of Dermatology, pgs 155-57, as evidence supporting this.
3. I respectfully must advise you that it was not my intent in this article to indicate that sulfur is toxic when applied topically at a concentration above 6%.
4. I was discussing an earlier report that topical sulfur had been "toxic" when applied at 6%, probably under occlusion, to an infant. This reported "toxicity" in this case may have been due to other causes or due to the exceptional, higher permeability to absorption of infant skin compared to that of young children and adults.
5. It was my intent then, and my opinion now, that sulfur has been safely applied topically, literally for centuries, at many concentrations, including those over 6%.

Best Available Copy

6. The U.S. Food and Drug Administration recognizes sulfur's safety at concentrations up to 10% without the supervision of a physician, and physician have safely used sulfur at higher concentrations.
7. In this application, it is my opinion that sulfur can be safely applied topically to unbroken skin at concentrations of at least up to 20%, except to children under 2 years of age.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application and any registration resulting therefrom.

Date:

1/27/05


Howard Maibach, Ph.D.